REMARKS

Claims 1-9 and 12-13 are pending herein. The Examiner has requested election of one invention, alleging that the application contains claims directed to patentably distinct inventions as follows:

Group I. Claims 1-9 drawn to a therapeutic composition comprising the anti-gluten egg yolk antibodies.

Group II. Claims 12-13 drawn to a method of treating celiac disease or preventing gluten uptake comprising administering a pharmaceutical composition comprising egg yolk comprising anti-gluten antibodies.

The Examiner states that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features which "define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art" (PCT Rule 13.2). The Examiner states that:

> The technical feature of the present invention is a composition comprising anti-gluten IgY antibodies. Ellis *et al.* teach anti-gluten antibodies that are raised against gliadin, a species of gluten, wherein the antibodies are polyclonal and monoclonal IgG antibodies (Gut 1998, 43:190-195, see entire document). Given the teaching by Ellis *et al.*, it would have been obvious to one of ordinary skill in the art at the time of the invention to raise IgY antibody against gliadin because IgY technology was well-known at the time of the invention as demonstrated by Lee (U.S. Patent No. 5,367,054, see entire document). In particular, given the teaching by Lee on the advantage of making IgY antibodies, i.e., that egg yolk is a very good source of specific antibodies (see column 1, lines 34-46), one of skill would have been motivated to make anti-gluten antibody in egg yolk.
>
> In view of the composition comprising the anti-gluten antibodies taught by Ellis *et al.* (see paragraph bridging pages 191-192) and the advantage and practicality in IgY production taught by Lee (see Background of the Invention and Figure 1), it would have been *prima facie* obviate to make an anti-gluten IgY antibody, in view of the evidence, especially in the absence of evidence to the contrary. Therefore, the technical feature of the present invention does not contribute over prior art and thus the unity of invention does not exist.

Applicants provisionally elect Group I (claims 1-9) for examination with traverse. With the election of Group I, Applicants request reconsideration of the Restriction Requirement imposed

upon Group II. Applicants reserve the right to pursue any unclaimed subject matter in one or more divisional or continuation applications.

Applicants have amended the claims to emphasize the relationship between the two Groups of claims. Claim 12 has been amended to recite a method of treating or ameliorating the symptoms of celiac disease or a gluten sensitive condition comprising the step of administering to a mammal in need thereof the pharmaceutical or nutraceutical composition or food product of claim 1. Claim 13 has been amended to recite a method of preventing gluten uptake in the digestive system of a mammal comprising the steps of administering to the mammal the pharmaceutical or nutraceutical composition or a food product of claim 1. No new matter has been added with the amendments made herein. Support resides in the as-filed specification on pages 3, 7 and 8.

Applicants refer to PCT Rule 13.4 stating that it is permissible "to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention." Accordingly, claims 1-9 directed to the product (i.e., the composition) are thus permissible together with claims 12-13 drawn to use of the product (i.e., method of treating or ameliorating the symptoms of celiac disease or a gluten sensitive condition, or preventing gluten uptake in the digestive system).

Applicants submit that a technical relationship between the Group I and II claims resides in the fact that the composition of Group I is required to practice the method of treating or ameliorating the symptoms of celiac disease or a gluten sensitive condition, or preventing gluten uptake in the digestive system of Group II, as specifically recited in amended claims 12 and 13. Thus, the claims of Groups I and II are related as product and method of use of product. As indicated in MPEP 806.05(h) "a product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process." The process as claimed cannot be practiced with a materially different product (the process requires a composition comprising anti-gluten egg yolk antibodies) and the product as

claimed cannot be used in a materially different process (the process requires an amount of the anti-gluten egg yolk antibodies which are capable of binding a component of gluten).

Applicants respectfully disagree with the Examiner's comment alleging that "the technical feature of the present invention does not contribute over the prior art" in accordance with PCT Rule 13.2. Applicants remind that the International Preliminary Report on Patentability dated October 19, 2006 considered all claims as meeting the requirements for novelty, inventive step and industrial applicability under Articles 33(2)-33(4) PCT.

Further, Applicants' claimed invention does not constitute a predictable use of prior art elements. Applicants have claimed a composition prepared using a process having a specific sequence of steps and for particular therapeutic uses, the entirety of which is not found in any of the cited references, taken singularly or in any combination. Ellis *et al.* relates to an assay including use of antibodies for detection of gluten in foods based on wheat, rye, barley and oats. Ellis *et al.* has no teachings related to a composition comprising anti-gluten egg yolk antibodies or use of same for treating celiac disease or a gluten sensitive condition, as recited in Applicants' claims 1, 12 and 13. None of the cited secondary references cure these deficiencies. Lee is cited for its teachings related to IgY technology; however, Applicants submit that Lee teaches a different series of steps and a different sequence, relating to only purification of immunoglobulin from egg yolk. The reference must provide not only every step, but also the specific sequence for preparation of the claimed composition. The cited website describing "Ora Mune Magna" advertises capsules of egg yolk anti-gluten antibody, but does not provide any indication of how the antibody might have been prepared. Applicants thus submit that a combination of the cited references would not equate to the claimed invention or render its results as predictable or obvious. Even if the cited references were combined, they do not teach or suggest the composition as prepared by the proper sequence of steps recited in Applicants' claims. The combination of the cited references is contraindicated, as born out by the above remarks.

For these reasons, Applicants submit that restriction between the claims of Groups I and II is inappropriate in view of the amendments and the clear relationship between the Group I and II claims.

In response to the requirement of species election, Applicants have elected anti-gliadin as the specific anti-gluten antibody. The claims readable thereon are claims 1-9 and 12-13.

In summary, based upon the above amendments and remarks, Applicants respectfully request reconsideration of the Restriction Requirement and simultaneous examination of all the Group I and II claims.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance and passage to issuance is respectfully requested.

Respectfully submitted,

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